(d) Reauthorization

(1) Consultation

In developing recommendations to present to the Congress with respect to the goals described in subsection (a), and plans for meeting the goals, for OTC monograph drug activities for the first 5 fiscal years after fiscal year 2025, and for the reauthorization of this subpart for such fiscal years, the Secretary shall consult with—

(A) the Committee on Energy and Commerce of the House of Representatives;

(B) the Committee on Health, Education, Labor, and Pensions of the Senate;

(C) scientific and academic experts;

(D) health care professionals;

(E) representatives of patient and consumer advocacy groups; and

(F) the regulated industry.

(2) Public review of recommendations

After negotiations with the regulated industry, the Secretary shall—

(A) present the recommendations developed under paragraph (1) to the congressional committees specified in such paragraph;

(B) publish such recommendations in the Federal Register;

(C) provide for a period of 30 calendar days for the public to provide written comments on such recommendations;

(D) hold a meeting at which the public may present its views on such recommendations; and

(E) after consideration of such public views and comments, revise such recommendations as necessary.

(3) Transmittal of recommendations

Not later than January 15, 2025, the Secretary shall transmit to the Congress the revised recommendations under paragraph (2), a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments.

(June 25, 1938, ch. 675, § 744N, as added Pub. L. 116–136, div. A, title III, § 3862, Mar. 27, 2020, 134 Stat. 468.)

Editorial Notes

REFERENCES IN TEXT

Section 3861(b) of the CARES Act, referred to in subsec. (a), probably means section 3861 of Pub. L. 116–136, div. A, title III, Mar. 27, 2020, 134 Stat. 458, which is set out as a note under section 379j–71 of this title. Section 3861 of Pub. L. 116–136 does not contain subsecs.

PART D—INFORMATION AND EDUCATION

§ 379k. Information system

The Secretary shall establish and maintain an information system to track the status and progress of each application or submission (including a petition, notification, or other similar form of request) submitted to the Food and Drug Administration requesting agency action.

(June 25, 1938, ch. 675, § 745, formerly § 741, as added Pub. L. 105–115, title IV, § 407(a), Nov. 21, 1997, 111 Stat. 2370; renumbered § 745, Pub. L. 110–316, title II, § 202(a), Aug. 14, 2008, 122 Stat. 3515.)

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE

Section effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105–115, set out as an Effective Date of 1997 Amendment note under section 321 of this title.

REPORT ON STATUS OF SYSTEM

Pub. L. 105–115, title IV, § 407(b), Nov. 21, 1997, 111 Stat. 2370, provided that not later than 1 year after Nov. 21, 1997, Secretary of Health and Human Services was to submit report to Congress on status of system to be established under this section, including projected costs of system and concerns about confidentiality.

§ 379k–1. Electronic format for submissions

(a) Drugs and biologics

(1) In general

Beginning no earlier than 24 months after the issuance of a final guidance issued after public notice and opportunity for comment, submissions under subsection (b), (i), or (j) of section 355 of this title or subsection (a) or (k) of section 262 of title 42 shall be submitted in such electronic format as specified by the Secretary in such guidance.

(2) Guidance contents

In the guidance under paragraph (1), the Secretary may—

(A) provide a timetable for establishment by the Secretary of further standards for electronic submission as required by such paragraph; and

(B) set forth criteria for waivers of and exemptions from the requirements of this subsection.

(3) Exception

This subsection shall not apply to submissions described in section 360bbb of this title.

(b) Devices

(1) In general

Beginning after the issuance of final guidance implementing this paragraph, presubmissions and submissions for devices under section 360(k), 360c(f)(2)(A), 360e(c), 360e(d), 360e(f), 360j(g), 360j(m), or 360bbb–3 of this title or section 262 of title 42, and any supplements to such presubmissions or submissions, shall include an electronic copy of such presubmissions or submissions.

(2) Guidance contents

In the guidance under paragraph (1), the Secretary may—

(A) provide standards for the electronic copy required under such paragraph; and

(B) set forth criteria for waivers of and exemptions from the requirements of this subsection.

(3) Presubmissions and submissions solely in electronic format

(A) In general

Beginning on such date as the Secretary specifies in final guidance issued under sub-

paragraph (C), presubmissions and submissions for devices described in paragraph (1) (and any appeals of action taken by the Secretary with respect to such presubmissions or submissions) shall be submitted solely in such electronic format as specified by the Secretary in such guidance.

(B) Draft guidance

The Secretary shall, not later than October 1, 2019, issue draft guidance providing for—

(i) any further standards for the submission by electronic format required under subparagraph (A);

(ii) a timetable for the establishment by the Secretary of such further standards; and

(iii) criteria for waivers of and exemptions from the requirements of this subsection.

(C) Final guidance

The Secretary shall, not later than 1 year after the close of the public comment period on the draft guidance issued under subparagraph (B), issue final guidance.

(June 25, 1938, ch. 675, §745A, as added Pub. L. 112–144, title XI, §1136, July 9, 2012, 126 Stat. 1123; amended Pub. L. 115–52, title II, §207, Aug. 18, 2017, 131 Stat. 1019.)

Editorial Notes

AMENDMENTS

2017—Subsec. (b)(3). Pub. L. 115–52 added par. (3).

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 2017 AMENDMENT

Amendment by title II of Pub. L. 115–52, effective Oct. 1, 2017, except that fees under subpart 3 of part C of this subchapter to be assessed for all submissions listed in section 379j(a)(2)(A) of this title received on or after Oct. 1, 2017, see section 209 of Pub. L. 115–52, set out as a note under section 379i of this title.

§ 379*l*. Education

(a) In general

The Secretary shall conduct training and education programs for the employees of the Food and Drug Administration relating to the regulatory responsibilities and policies established by this chapter, including programs for—

(1) scientific training;

(2) training to improve the skill of officers and employees authorized to conduct inspections under section 374 of this title;

(3) training to achieve product specialization in such inspections; and

(4) training in administrative process and procedure and integrity issues.

(b) Intramural fellowships and other training programs

The Secretary, acting through the Commissioner, may, through fellowships and other training programs, conduct and support intramural research training for predoctoral and postdoctoral scientists and physicians. Any such fellowships and training programs under this section or under section 379dd(d)(2)(A)(ix) of this title may include provision by such scientists and physicians of services on a voluntary and uncompensated basis, as the Secretary determines appropriate. Such scientists and physicians shall be subject to all legal and ethical requirements otherwise applicable to officers or employees of the Department of Health and Human Services.

(June 25, 1938, ch. 675, §746, formerly §742, as added Pub. L. 105–115, title IV, §408(a), Nov. 21, 1997, 111 Stat. 2371; amended Pub. L. 110–85, title VI, §601(c), Sept. 27, 2007, 121 Stat. 897; renumbered §746, Pub. L. 110–316, title II, §202(a), Aug. 14, 2008, 122 Stat. 3515.)

Editorial Notes

PRIOR PROVISIONS

A prior section 746 of act June 25, 1938, was renumbered section 749 and is classified to section 379*o* of this title.

AMENDMENTS

2007—Subsec. (b). Pub. L. 110–85 inserted at end ''Any such fellowships and training programs under this section or under section 379dd(d)(2)(A)(ix) of this title may include provision by such scientists and physicians of services on a voluntary and uncompensated basis, as the Secretary determines appropriate. Such scientists and physicians shall be subject to all legal and ethical requirements otherwise applicable to officers or employees of the Department of Health and Human Services.''

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE

Section effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105–115, set out as an Effective Date of 1997 Amendment note under section 321 of this title.

PART E—ENVIRONMENTAL IMPACT REVIEW

§ 379*o*. Environmental impact

Notwithstanding any other provision of law, an environmental impact statement prepared in accordance with the regulations published in part 25 of title 21, Code of Federal Regulations (as in effect on August 31, 1997) in connection with an action carried out under (or a recommendation or report relating to) this chapter, shall be considered to meet the requirements for a detailed statement under section 4332(2)(C) of title 42.

(June 25, 1938, ch. 675, §749, formerly §746, as added Pub. L. 105–115, title IV, §411, Nov. 21, 1997, 111 Stat. 2373; renumbered §749, Pub. L. 110–316, title II, §202(a), Aug. 14, 2008, 122 Stat. 3515.)

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE

Section effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105–115, set out as an Effective Date of 1997 Amendment note under section 321 of this title.